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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,709	08/03/2000	Satoshi Koizumi	766.37	9510

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FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/06/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/631,709

Applicant(s)

KOIZUMI

Examiner

Sandra Saucier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,9-22 and 24-41 is/are pending in the application.
- 4a) Of the above claim(s) 18,19,21,22,33 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,9-17,20,24-32 and 35-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 August 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 10.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 2, 3, 9-22, 24-41 are pending. Claims 2, 3, 9-17, 20, 24-32, 35-41 are considered on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3, 24-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/068528. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same process of generating GDP-4-keto-6-deoxymannose.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. This rejection will be reassessed at time of allowance.

Claim Rejections – 35 USC § 102

Claims 2, 10, 13–15, 17, 20, 35–38 and 41 remain/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 99/36555 [IDS] or EP 870 841 [IDS].

The claims are directed to a process of making GDP fucose by allowing a GTP precursor, a saccharide and enzyme sources capable of forming GDP–4–keto–6–mannose and converting the GDP–4–keto–6–deoxymannose to GDP fucose and recovering the GDP fucose therefrom.

WO 99/36555 disclose in Fig. 16 and elsewhere that GDP, which is a precursor of GTP, a saccharide such as mannose or glucose when incubated with an enzyme source in a medium forms GDP–4–keto–6–deoxymannose which is converted to GDP fucose. In Figure 16, the GDP–fucose is shown to be further used to fucosylate a substrate; however, on page 29, line 3 and other places, recovery of the GDP–fucose is clearly explained.

EP 870 841 discloses a process for production of GDP fucose, example 16. A GTP precursor (GMP) and a saccharide (mannose) are incubated with enzyme sources which produce GDP–fucose via GDP–4–keto–6–mannose.

Response to Arguments

Applicant's arguments filed 7/17/03 have been fully considered but they are not persuasive.

Applicant argues that WO 99/36555 does not use the whole culture broth in the reaction, while applicants use “a concentrated product of the culture broth” by which they intend to mean a concentrated whole culture broth. A

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concentrated product is just that, a product of the culture broth which has been concentrated. This may be any product. No mention of lack of purification or extent of purification of the product is in the claim nor any other limitation which would limit applicants' claim to a concentrated, unpurified or whole culture broth. Thus, the argument is unpersuasive. Applicants seem to claim, in one embodiment, that the culture broth, which would not necessarily contain the cells, contains the necessary enzymes for the conversion. This seem highly unlikely, unless the cells are first lysed or permeabilized in the culture broth. In fact the examples in the instant specification use (wet) packed cells which have been frozen and thawed, presumably lysing them and releasing the enzymes. This is not a "concentrated culture broth". This appears to be the same procedure described in WO 99/36555, last paragraph on page 26, where the cells are permeabilized. Please note that no washing of the cells is described, and on the next page, p. 27, l. 10, wet wt/vol is discussed, which implies a centrifugation or sedimentation step. This appears to be essentially the same method as the method of applicants' examples. While applicants' method may indeed have some differences from the prior art, these differences have not been clearly claimed. Thus, the claimed method is still considered to be anticipated or at the very least, obvious over this reference.

Please note that a culture medium or broth can be interpreted to contain a suspension of cells *or* can be the medium or broth before the addition of cells or after the removal of cells, and thus, can be devoid of cells. Attention to applicants' examples, which exemplify packed cells subjected to freeze-thawing ostensibly to lyse the cells, when amending claims might advance prosecution. Packed cells are not necessarily a concentrated product of the culture broth. If applicants mean packed cells applicants should so state.

Applicants argue that EP 0 870 841 does not teach the accumulation of GKDM prior to conversion to GDP-fucose. Please note "accumulation" has no quantity limitation. Accumulation could be just one molecule "accumulated" prior to conversion to GDP fucose. It has not been demonstrated that EP 0 870 841 does not "accumulate" any GKDM prior to conversion to GDP-fucose. A

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sequential addition of enzyme sources (then adding...) clearly claimed as such, if this is supported by applicants' specification, might overcome the anticipatory rejection over EP 0 870 841. Please note that no sequential physical steps are present in the claimed method so as to exclude the mixture of all of the reactants and enzymes in one pot and at one time.

Claim Rejections – 35 USC § 103

Claims 2, 9-17, 20, 35-41 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/36555 [IDS] in combination with EP 870 841 [IDS].

The claims are directed to an enzymatic process of making GDP fucose by allowing a GTP precursor, a saccharide and enzyme sources to produce GTP and then using the GTP to form GDP-4-keto-6-deoxymannose, converting the GDP-4-keto-6-deoxymannose to GDP fucose and recovering the GDP fucose therefrom.

The references are relied upon as explained below.

WO 99/36555 disclose in Fig. 1 and on page 2 that GDP mannose is provided and is converted to GDP fucose.

EP 870 841 teaches a process of producing sugar nucleotides from a sugar and a nucleotide precursor (page 5, l. 25) using recombinant microbes. In particular, in the production of GDP-mannose, example 14, GMP (nucleotide precursor) and mannose (sugar) are present in the incubation medium with *C. ammoniagenes*. On page 5, it is particularly disclosed that the use of expensive starting materials such as nucleotide triphosphates (GTP) are not necessary and that use of a sugar and a nucleotide precursor can be used in the production of, as in example 16, GDP-fucose. Microbes may be *E. coli* or *Corynebacterium ammoniagenes* (page 5, l. 25-49, page 9, l. 51-57)).

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The addition of the method steps of EP 870 841 to the method of WO 99/36555 would have been obvious particularly in light of the direct suggestion on page 5 of '841 to generate GTP for use in the production of GDP-fucose from mannose and GMP as shown in example 16. This manner of production of GTP which can be usefully incorporated into other processes is well known in the art (page 18, l. 18 and l. 27).

Claims 3, 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO99/09180 [N] in combination with EP 870 841 [IDS].

The claims are directed to the production and recovery of GDP-4-keto-6-deoxymannose using enzyme sources and a GTP precursor and a saccharide.

WO 99/09180 discloses a method of producing GDP-4-keto-6-deoxymannose from GDP-mannose using an enzyme source (dehydratase) present in recombinant *E. coli* (Example 11). The GDP-4-keto-6-deoxymannose is recovered.

The reference lacks the use of a GTP precursor (GMP) and a saccharide (mannose) as the starting materials to make the GDP-mannose starting material of the reference.

EP 870 841 teaches a process of producing sugar nucleotides from a sugar and a nucleotide precursor (page 5, l. 25) using recombinant microbes. In particular, in the production of GDP-mannose, example 14, GMP (nucleotide precursor) and mannose (sugar) are present in the incubation medium with *C. ammoniagenes*. On page 5, it is particularly disclosed that the use of expensive starting materials such as nucleotide triphosphates (GTP) are not necessary and that use of a sugar and a nucleotide precursor can be used in the production of GDP-mannose. Microbes may be *E. coli* or *Corynebacterium ammoniagenes* (page 5, l. 25-49, page 9, l. 51-57)).

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The addition of the method steps of EP 870 841 to the method of WO 99/09180 would have been obvious particularly in light of the direct suggestion on page 5 of '841 to generate GTP for use in the production of GDP-saccharides from mannose and GMP. This manner of production of GTP which can be usefully incorporated into other processes is well known in the art (page 18, l. 18 and l. 27).

One of ordinary skill in the art would have been motivated at the time of invention to make this addition to the method in order to obtain the resulting compound as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 5:00PM Monday and Tuesday and 8:30-noon on Wednesday.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized, flowing script.

Sandra Saucier
Primary Examiner
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October 1, 2003